REMARKS

In an Advisory Action dated November 4, 2008, the Examiner indicated that the amendments filed on October 13, 2008 would not be entered. Accordingly, claims 1-29 are pending and stand rejected. Applicants respectfully request reconsideration of the present application in view of the above amendments and following remarks.

Amendments to the Claims

Applicants amend independent claim 1 to clarify that the cell growth conduit flap communicates biological materials to a tissue defect in the meniscus. Applicants also amend independent claims 21 and 25 to clarify that cells and nutrients travel to the defect in the meniscus through the cell growth conduit flap. Support for these amendments can be found throughout the specification, for example, at paragraphs 0032-0035 of the published application. Claim 4 is amended to correct a typographical error. Applicants also add new claims 30-41 which recite the features previously recited in claims 7-10, 19 and 20. Support for these new claims can also be found throughout the specification, for example, at paragraphs 0033, 0036, and 0048-0051 of the published application. No new matter is added.

Rejections Pursuant to 35 U.S.C. §102

Malaviya '797

The Examiner rejects claims 1, 2, 4-8, 10-17, and 20 pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Publication No. 2003/0036797 of Malaviya et al. ("Malaviya '797"). Applicants respectfully disagree.

Claim 1 recites that the cell growth conduit flap contacts a tibial surface, extends to the synovium, and communicates biological materials to a tissue defect in the meniscus. Applicants submit that claim 1 distinguishes over Malaviya '797 and represents allowable subject matter.

At the outset, the device disclosed by Malaviya '797 fails to teach or suggest a cell growth conduit flap. Malaviya '797 discloses a device 230 comprising a plurality of conical compartments disposed between "covers" 232, 234. (*See* Malaviya '797 at Par. 0156.) There is no teaching or suggestion that the covers 232, 234 are anything more than an outer cover for the conical compartments disposed therebetween. Therefore, Malaviya '797 fails to teach or suggest a cell growth conduit flap.

Moreover, Malaviya '797 fails to teach or even suggest a cell growth conduit flap that extends to the synovium, as required by claim 1. Indeed, the Examiner has previously admitted that "Malaviya ['797] does not explicitly disclose that the cell growth conduit flap is in contact with the synovium." Nevertheless, the Examiner asserts that "claim 1 is an apparatus claim and this limitation is directed to the intended use of the device." Applicants respectfully note that the Manual of Patent Examining Procedure (MPEP) makes it clear that there is nothing inherently wrong with defining some parts of an invention in functional terms:

> A functional limitation ***must be evaluated*** and considered ***just like any other limitation of the claim***, for what it fairly conveys to a person of ordinary skill in the art. MPEP 2173.05(g) (Emphasis added)

The Examiner has failed to follow this guidance and has instead resorted to an argument that the "cell growth conduit flap of Malaviya is entirely capable of being positioned such that the flap extends to the synovium." However, according to the teachings of Malaviya '797, the covers 232, 234, which the Examiner argues form the claimed cell growth conduit flap, cannot extend to the synovium. Malaviya '797 teaches that the "adjacent radially outer portion of the original meniscus" is retained and contacts the device. The retained radially outer portion of the original meniscus thus prevents the device from being positioned in a manner that would allow the covers 232, 234 to extend to the synovium. Moreover, even if the device could be positioned such that the covers 232, 234 extended to the synovium, in such a position the device would no longer "conform to the space into which it is inserted such that the surrounding tissue of the remaining meniscus is in contact with the device," as taught by Malaviya '797. (*See* Malaviya '797 at Par. 0018.) Therefore, Malaviya '797 fails to teach or suggest a cell growth conduit flap extending to the synovium.

Furthermore, claim 1 also recites that the cell growth conduit flap communicates biological materials to a tissue defect in the meniscus, a feature completely absent from the Malaviya '797 reference. The Examiner argues that the "flaps have an open space to communicate biological materials from the vascularized area in which it contacts." Applicants note that because Malaviya's device does not extend to the synovium, as discussed above, the "vascularized area in which it contacts" is actually the "vascular rich outer portion of the meniscus," not the synovium. (*See* Malaviya '797 at Par. 0024.) Regardless, Malaviya fails to teach or suggest that the covers 232, 234 communicate biological materials. Malaviya teaches that blood flow is *channeled* by the device. (*Id.*) Malaviya later clarifies that fluids can

"infiltrate open space" between the upper and lower covers. (*Id.* at Par. 0153.) In contrast, Applicants' invention provides a cell growth conduit flap with material properties and a structure which allow the passage of biological materials. (*See* published application at Par. 0033.) Malaviya '797 merely teaches that fluids are channeled through the open space between layers of the device. Malaviya '797 thus fails to teach a cell growth conduit flap that communicates biological materials, as required by claim 1.

Accordingly, independent claim 1 distinguishes over Malaviya '797 and represents allowable subject matter. Claims 2 and 4-20 likewise distinguish over Malaviya '797 by virtue of their dependence on claim 1.

Malaviya '344

The Examiner rejects claims 1 and 18 pursuant to 35 U.S.C. §102(e) as being anticipated by U.S. Publication No. 2004/0143344 of Malaviya et al. ("Malaviya '344"). Applicants respectfully disagree. As discussed above, claim 1 recites a cell growth conduit flap contacting a tibial surface, extending to the synovium, and communicating biological materials to a tissue defect in the meniscus. For all the reasons discussed above with respect to Malaviya '797, Malaviya '344 fails to teach or suggest the invention as claimed. In particular, like Malaviya '797 from which it is a continuation-in-part, Malaviya '344 does not teach or suggest a cell growth conduit flap that contacts a tibial surface and *extends to the synovium*. Malaviya '344 discloses additional details regarding the cover 12 of the device. However, as shown in FIG. 8, Malaviya '344 continues to teach that the outer portion of the meniscus is retained and the device is sutured to the outer portion of the meniscus by sutures 30. (Malaviya '344 at Par. 0045 and FIG. 8.) Moreover, the only purpose disclosed by Malaviya '344 for any extension of the cover is to facilitate fixation of the device. For example, Applicants note that FIG. 8A shows a "wing" of the implant extending beyond the edge of the meniscus. However, Malaviya '344 teaches only that the "wing" can be used to "fix the implant directly to the patient's tibia 70, for example by inserting a screw 72 through the wing 25 and into the tibia 70." (Malaviya '344 at Par. 0073.) There is no teaching or suggestion that the "wing" or any other extension of the cover extends to the synovium.

Furthermore, as discussed above with respect to Malaviya '797, Malaviya '344 also fails to teach or suggest a cell growth conduit flap communicating biological materials. The Examiner argues that "the cover materials disclosed by Malaviya '344 and '797, including ECM, bioremodelable material, and biocompatible polymers are all capable of communicating

biological materials to the tissue defect in the meniscus." As noted above, a functional limitation must be evaluated and considered just like any other limitation of the claim. (*See* MPEP 2173.05(g).) There remains no teaching or suggestion in either Malaviya '344 or '797 that biological materials are communicated by the covers taught by either reference. Malaviya '344 merely teaches that the layered cover comprises sheets of SIS. The disclosure of Malaviya '344 provides no teaching or suggestion that the laminated layers of SIS communicate biological materials to a tissue defect or even that they are capable of communicating biological materials. Indeed, Malaviya '344 only discloses the layered cover as a means for containing and anchoring the tissue regeneration material within the cover. (*See* Malaviya '344 at Par. 0043, 0045.)

Accordingly, independent claim 1 distinguishes over Malaviya '344 and represents allowable subject matter. Claim 18 depends from claim 1 and therefore distinguishes over Malaviya '344 for all the reasons discussed with respect to claim 1.

Rejections Pursuant to 35 U.S.C. §103

Malaviya '797

The Examiner rejects claims 9, 21, 25, and 27 pursuant to 35 U.S.C. §103(a) as being unpatentable over Malaviya '797. Applicants respectfully disagree with the Examiner's rejection.

At the outset, Applicants note that claim 9 depends from claim 1 and therefore distinguishes over Malaviya '797 for all the reasons discussed above with respect to claim 1. In brief, Malaviya '797 neither teaches nor suggests a cell growth conduit flap that contacts a tibial surface, extends to the synovium, and communicates biological materials, as required by claim 1.

Claims 21 and 25 recite that the cell growth conduit flap is positioned in contact with a tibial surface and the synovium. The Examiner admits that "Malaviya does not explicitly disclose that the cell growth conduit flap is in contact with the synovium." The Examiner asserts that Malaviya '797 states that "one or more of the layers of the material forming the upper cover or the lower cover may be formed to provide tabs extending away from the device to facilitate attachment to the surrounding tissue." The Examiner then argues that the tabs "could extend to the synovium." However, claims 21 and 25 also recite that "the cell growth conduit flap allows cells and nutrients to travel *through* the cell growth conduit flap to the defect in the meniscus." Malaviya '797 teaches only that the tabs are fastened to surrounding tissue. (See Malaviya '797 at Par. 0169- 0170.) There is no teaching or suggestion in Malaviya '797 that the tabs allow cells and nutrients to travel to the defect in the meniscus, much less that cells and nutrients travel

through the tabs themselves. Malaviya '797 merely teaches that blood flow is *channeled* by the device. (*See* Malaviya '797 at Par. 0024.) Malaviya later clarifies that that fluids will "infiltrate open space" between the upper and lower covers. (*Id.* at Par. 0153.)

In contrast, Applicants' invention provides a cell growth conduit flap with material properties and a structure that allow fluids and/or cells to move through the conduit flap. (*See* published application at Par. 0033.) Malaviya '797 teaches that fluids are simply channeled through the open space between layers of the device and thus fails to teach a cell growth conduit flap that communicates biological materials, as required by claims 21 and 25. Furthermore, as discussed above, Malaviya '797 teaches that the "adjacent radially outer portion of the original meniscus" is retained and contacts the device. The radially outer portion of the original meniscus thus prevents the device from extending to the synovium. As such, Malaviya '797 not only does not teach or suggest the features recited in claims 21 and 25, but effectively teaches away from the instant invention.

Claim 27 depends from claim 25 and therefore distinguishes over Malaviya '797 for all the reasons discussed above with respect to claim 25. In addition, claim 27 recites that the cell growth conduit flap provides a conduit that enables cells and nutrients to travel *from the synovium* to the tissue defect in the meniscus. As discussed above, Malaviya '797 fails to teach or suggest a cell growth conduit flap that even extends *to the synovium*, much less a cell growth conduit flap that provides a conduit enabling cells and nutrients to travel *from the synovium* to a tissue defect in the meniscus.

Accordingly, claims 9, 21, 25, and 27 distinguish over Malaviya '797 and represent allowable subject matter.

Malaviya '797 in view of Li

The Examiner rejects claims 22, 23, 28, and 29 pursuant to 35 U.S.C. §103(a) as being unpatentable over Malaviya '797 in view of US Patent No. 4,790,819 of Li et al. ("Li"). Applicants respectfully disagree.

Claims 22-23 and claims 28-29 depend from claims 21 and 25, respectively, and therefore distinguish over Malaviya '797 for all the reasons discussed above with respect to claims 21 and 25. The Examiner admits that Malaviya '797 does not disclose the rasping step recited in claims 22 and 23. The Examiner relies on Li to teach the rasping step. Although Li teaches "using an arthroscopy rasp to abrade the superior and inferior parameniscal synovium," Li does not remedy

the deficiencies of Malaviya '797 with respect to the features recited in claim 21 and 25 from which claims 22-23 and 28-29 depend. (See Li at Col. 1, lines 27-31).

Li discloses "a delivery device for depositing an exogenous fibrin clot into a wound site during an arthroscopic surgical operation." (Li at Abstract). As discussed above, claims 21 and 25, as amended, recite positioning the cell growth conduit flap in contact with the synovium. In the background of the invention, Li discloses "using an arthroscopy rasp to abrade the superior and inferior parameniscal synovium to increase blood supply to the meniscal tear." (Li at Col. 1, lines 27-31). However, Li does not teach or suggest depositing the fibrin clot material in contact with the synovium. Li merely discloses injecting "a quantity of fibrin clot material into the meniscle tear within the wound site." (Li at Col. 6, lines 63-65). In addition, Li does not disclose using the rasping step in combination with depositing the fibrin clot material. Indeed, Li's invention represents an improvement to methods that require rasping the synovium to create a fibrin clot. Regardless, Li fails to remedy the deficiencies of Malaviya '797 because Li fails to teach or suggest that the fibrin clot material is placed in contact with the synovium. Claims 22, 23, 28, and 29 therefore distinguish over Malaviya '797 and Li and represent allowable subject matter.

Malaviya '344 in view of Malaviya '444

The Examiner rejects claim 19 pursuant to 35 U.S.C. §103(a) as being unpatentable over Malaviya '344 in view of US Patent Publication No. 2003/0044444 of Malaviya et al. ("Malaviya '444"). Applicants respectfully disagree.

Dependent claim 19 recites that "the density of the cell growth conduit flap is in the range of about 150 mg/cc to 350 mg/cc." The Examiner admits that Malaviya '344 "does not disclose that the density is in the range of about 150-350 mg/cc." The Examiner relies on Malaviya '444 to teach that "an ECM scaffold can be made to have a desired density." Although Malaviya '444 teaches the steps of "fabricating a porous scaffold with a desired pore size and density," Malaviya '444 fails to teach or suggest the claimed density range.

Regardless, Malaviya '444 does not remedy the deficiencies of Malaviya '344 with respect to the features recited in independent claim 1, from which claim 19 depends. Malaviya '444 teaches a porous implantable scaffold, but fails to teach a cell growth conduit flap attached to a tissue repair scaffold. Consequently, the combination of Malaviya '344 and Malaviya '444 fails to teach a cell growth conduit flap that extends to the synovium and communicates

biological materials to a tissue defect in the meniscus. Claim 19 therefore distinguishes over Malaviya '344 and Malaviya '444 and represents allowable subject matter.

New Claims 30-37

Applicants submit that new claims 30-41 represent allowable subject matter. At the outset, claims 30-41 depend directly or indirectly from claims 1, 21, or 25 and therefore distinguish over the cited references for all the reasons discussed above. Claims 30-33 also depend from claim 19 and therefore distinguish over the cited references for all the reasons discussed above with respect to claim 19. Moreover, Malaviya '444 discloses only the fabrication of a scaffold of comminuted SIS material. Although the Examiner has relied on Malaviya '444 to teach that "an ECM scaffold can be made to have a desired density," Malaviya '444 fails to teach or suggest the fabrication of a scaffold or tissue flap of a desired density including the materials recited by claims 30-33. Accordingly, claims 30-33 distinguish over the cited references and represent allowable subject matter.

Claims 34-37 depend from claim 20, which recites that the *cell growth conduit flap* has a void volume in the range of about 50% to 95%. None of the cited references teach or suggest that any portion of their respective devices has a void volume as required by claim 20, much less a cell growth conduit flap that has a void volume as required. The Examiner asserts that the void volume recited by claim 20 is shown in FIG. 29 of Malaviya '797. Applicants respectfully disagree. The conical shells or compartments 250 disclosed by Malaviya '797 and shown in FIG. 29 are not a cell growth conduit flap. Indeed, the Examiner asserts that the covers 232, 234 form the claimed conduit flap, not the compartments 250. Malaviya '797 fails to teach or suggest that the covers 232, 234 have a void volume of the claimed range. Malaviya '797 discloses that the covers are formed by laminating layers of SIS material under heat and pressure. (*See* Malaviya '797 at Par. 0027.) Thus, Malaviya '797 fails to teach or suggest a cell growth conduit flap having a void volume as required by claim 20. Moreover, none of the references cited by the Examiner teaches or suggests a cell growth conduit flap having a void volume as claimed and also including the materials recited by claims 34-37. Accordingly, claims 34-37 distinguish over the cited references and represent allowable subject matter.

Claims 38-41 depend from claims 21 and 25 and therefore distinguish over the cited references for all the reasons discussed above with respect to claims 21 and 25. Also, claims 38 and 40 recite that the density of the cell growth conduit flap is in the range of about 150 mg/cc to

350 mg/cc. As discussed above with respect to claim 19, the cited references fail to teach or suggest the claimed density range. Likewise, claims 39 and 41 recite that the cell growth conduit flap has a void volume in the range of about 50% to 95%. As discussed above, the cited references fail to teach or suggest the claimed range of void volumes. Accordingly, claims 38-41 distinguish over the cited references and represent allowable subject matter.

Conclusion

Applicants submit that all pending claims are allowable, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed necessary to expedite prosecution of this application.

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Respectfully submitted,

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